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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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**DETERMINING TECHNICAL SECTION REQUIREMENTS FOR NEW ANIMAL DRUG  
PRODUCT APPROVAL**

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**I. PURPOSE**

The purpose of this document is to explain:

- Why we encourage sponsors to request a presubmission conference to determine technical section requirements,
- Timing considerations for that discussion, and
- What we will do if sponsors choose not to request a presubmission conference (PSC), request a limited PSC that does not address all technical sections, or change the scope of the project after a PSC.

This document applies to:

- All investigational new animal drug (INAD) or new animal drug application (NADA) projects that will culminate in original approvals, including Animal Drug Availability Act of 1996 (ADAA) combinations, and
- INAD, NADA, or abbreviated new animal drug application (ANADA) projects that will culminate in supplemental approvals that require safety and/or effectiveness data (including bioequivalence).<sup>1</sup>

This document does not apply to labeling supplements or Chemistry, Manufacturing, and Controls (CMC) supplements.<sup>2</sup>

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<sup>1</sup> Category II supplements as described in 21 CFR 514.106(b)(2)

<sup>2</sup> Category I supplements as described in 21 CFR 514.106(b)(1)

## II. THE IMPORTANCE OF A PRESUBMISSION CONFERENCE TO DETERMINE TECHNICAL SECTION REQUIREMENTS

For each new project defined above in the Purpose section, the assigned project manager (PM) will encourage the sponsor to request a PSC to determine the requirements for each applicable technical section for the project.<sup>3</sup> The Office of New Animal Drug Evaluation (ONADE) tasked the PM teams with this responsibility for several reasons:

- PSCs are an opportunity for the Center for Veterinary Medicine (CVM) and the sponsor to reach agreement on the overall regulatory pathway,
- PSCs allow CVM and the sponsor to create shared expectations, ideally early in development, regarding data or information required to support approval, and
- PSCs provide a forum for CVM and the sponsor to confirm any interdependencies that may exist between technical sections.

In processing the PSC request,<sup>4</sup> the PM:

- Identifies the project team; in addition to the PM, the project team consists of at least one representative from each team involved in the review of each applicable major technical section,
- Notifies the project team of the project initiation through consult requests, and
- Works with the project team to determine the technical section requirements for approval.

The project team determines technical section requirements based on the project scope (e.g., indication, species/class, dosage form, etc.), as provided by the sponsor. Determining technical section requirements means that the project team will determine for each applicable technical section whether:

- No new submission is required (e.g., the technical section is not affected by a supplemental change, or the sponsor is able to reference a completed technical section from another application),
- New submission(s) are required to complete the technical section, or
- CVM is unable to make a determination, because the sponsor needs to better define the scope of the project.

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<sup>3</sup> An applicable technical section is a technical section required for that type of project. For example, Human Food Safety is not an applicable technical section for a companion animal project.

<sup>4</sup> See 1243.3024 Scheduling and Holding Meetings with Outside Parties

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### **III. TIMING CONSIDERATIONS FOR A PRESUBMISSION CONFERENCE TO DETERMINE TECHNICAL SECTION REQUIREMENTS**

The first PSC for the project will normally be the meeting in which CVM and the sponsor determine technical section requirements. When a sponsor identifies in eSubmitter that a meeting is the first PSC, they can access templates allowing them to share their development plan and request input across all applicable technical sections without requiring all representatives to be present for discussion in the meeting. PMs will encourage sponsors to take advantage of this option.

For some projects, the sponsor may identify a narrow aspect of a technical section (e.g., carcinogenicity concerns or anticipated withdrawal time) as “make-or-break” for the project, and desire a first PSC focused solely on that specific aspect. In these cases, the PM and sponsor, in coordination with the PM’s team leader, may agree that a PSC to discuss the development plan across all technical sections will be held after the sponsor has confirmed the conclusion for their “make-or-break” issue. In these cases, the PM will work with the sponsor on how to submit their various PSC requests in eSubmitter.

### **IV. WHEN A SPONSOR DOES NOT REQUEST A PRESUBMISSION CONFERENCE, OR DOES NOT ADDRESS REQUIREMENTS ACROSS ALL TECHNICAL SECTIONS**

For some projects, the sponsor may proceed through development without requesting a PSC, or may request a limited PSC that does not address all applicable technical sections. In these cases, the PM will:

- Continue to encourage the sponsor to request a PSC to discuss their development plan across all applicable technical sections, or the applicable technical section(s) not yet discussed. As stated above, this is ONADE’s preferred approach for establishing shared expectations with the sponsor.
- Confirm technical section status with the project team during the end game meeting.<sup>5</sup> The “end game” in this context may refer to the actual end game (CVM received the last P submission for the project) or the end game as anticipated by the sponsor (CVM received what the sponsor believes to be the last P submission).

### **V. WHEN THERE ARE CHANGES TO THE SCOPE OF A PROJECT AFTER A PRESUBMISSION CONFERENCE**

When a sponsor identifies in eSubmitter that a meeting proposal represents a change to aspects of the project discussed in a previous meeting (e.g., changes to formulation, dosage form, dose, duration, route of administration, species and class, indication, or science/regulatory policy), they have the option to request revisiting their development plan across all applicable technical sections based on the change. If they choose this option, as with the first PSC, they can access templates allowing them to share their updated development plan and request input across all applicable

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<sup>5</sup> See 1243.3051 Verifying Scope and Technical Section Status for Phased Review (INAD) Projects in the End Game  
**Responsible Office: Office of New Animal Drug Evaluation**  
**Date: May 21, 2019**

technical sections without requiring all representatives to be present for discussion in the meeting. PMs will encourage sponsors to take advantage of this option.

If the sponsor chooses not to revisit their development plan across all applicable technical sections, the PM will confirm technical section status with the project team in the end game meeting. The “end game” in this context may refer to the actual end game or the end game as anticipated by the sponsor.

## **VI. REFERENCES**

CVM Program Policies and Procedure Manual

1243.3024 Scheduling and Holding Meetings with Outside Parties

1243.3051 Verifying Scope and Technical Section Status for Pioneer Phased Review (INAD) Projects in the End Game

## **VII. VERSION HISTORY**

June 9, 2011 – Original version

May 13, 2019 – Updated to remove specific procedures related to PSCs which were added to 1243.3024, and to remove the requirement for the PM to hold project team meetings under a Q submission (separate from the end game meeting) when the sponsor does not request a PSC at the project’s beginning or after changing the scope.